(1) 10 Jen.

EFFICACY REVIEW

DATE: IN 3-16-01 OUT 4-26-01

PETITION OR EXP. PERMIT NO. PATE DIV. RECEIVED March 14, 2001 PATE OF SUBMISSION March 9, 2001 PATE SUBMISSION ACCEPTED PATE PRODUCT(S): (I,)D, H, F, N, R, S PATA ACCESSION NO(S). None: D273487; S594144; Case# 068948; AC:161 PRODUCT MGR. NO. 03-Layne/DeLuise
March 9, 2001 OATE SUBMISSION ACCEPTED TYPE PRODUCT(S): (I,)D, H, F, N, R, S OATA ACCESSION NO(S). None; D273487; S594144; Case# 068948; AC:161
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PRODUCT MGR. NO03-Layne/DeLuise
RODUCT NAME(S)Unicorn .50% Permethrin Granules
COMPANY NAMEUnicorn Laboratories
SUBMISSION PURPOSE Provide references in support of me-too regis-
tration of a new product containing an old chem-
ical on the basis of the cite-all method.
CHEMICAL & FORMULATION <u>Permethrin 0.50%</u> \(\text{ready-to-use granular of unknown bulk density} \)

CONCLUSIONS & RECOMMENDATIONS The only reference for a company that produces permethrin products that is applicable to cite-all support for the registration of the subject product is that to Agrevo Enviromental Health, which following merger with Rhône-Poulenc does business under the name Aventis Environmental Science USA LP, since they produce the only other 0.5% permethrin granular formulation that is an active registration. In fact, there are only 5 active product registrations for granular permethrin for use as a lawn care application, and none of the other 4 are produced by registrants listed in the application, and all of them have 0.25% active ingredient rather than 0.50%. Furthermore, the references to some of the permethrin producing companies are not complete. The Miller WC Chemical Company could not be identified on REFS without looking at the 109 company names containing "Miller" as a part of the corporate name, it being the 86th. Also, due to recent mergers, 3 of the referenced company names have either no registrations or no active registrations and 3 of the remaining 4 are not unique in the names and company numbers, so that some of the numbers under these company names have registered products, some have no active registrations and some have no products at all, according (to be cont'd)

to REFS. The details are as follows:

Coopers Animal Health, 2 company numbers, no active products FMC Corporation Agricultural Products Group, 1 company number, 1 granular permethrin but not applicable to the subject product due to active ingredient concentration

Agrevo Environmental Health, 2 company numbers, 1 with no

active registrations

McLaughlin Gormley King Company, 1 company number with active registrations

Miller W C Chemical Company, no registrations Zeneca Ag Products, no active registrations

Sandoz Agro, Incorporated, 9 company numbers, 7 of which have no products, the other 2 have no active registrations.

As near as can be determined, the applicable company numbers which the registrant intended to reference are: Coopers Animal Health, 59 and 53218, the former numbers have all been cancelled and consist of 25 transfers to Schering-Plough Corporation and 6 Section 24(c), the remaining 75 having been cancelled outright. There are no granular formulations among them. The latter number consists entirely of 8 24(c) registrations, all cancelled.

FMC Corporation Agricultural Products Group, 279, the only applicable product being EPA Reg. No. 279-3059, "Pounce 1.5G Insecticide", which has 1.5% permethrin as the active ingredient.

Agrevo Environmental Health, 4816, with 558 cancelled, including 231 transfers to Aventis Environmental Science USA LP and 68 24(c) registrations, the remaining 259 having been cancelled outright. There are no granular formulations among the transferred products. The other number, 10370, with 238 products cancelled, including 89 transfers to Aventis Environmental Science USA LP, the remaining 149 having been cancelled outright. are no granular permethrin formulations among those transferred.

McLaughlin Gormley King Company, 1021, with 1081 products, 12 of which have been transferred to a number of different companies, including Aventis Environmental Science USA LP and 7 are 24(c) registrations. Of the 284 active registrations, there are no granular permethrin formulations, nor are there among the transferred.

Miller W C Chemical Company, 2791, no products found for this

company, according to REFS.

Zeneca Ag Products, 10182, 1100 products, including 256 that are active, consisting of 1 Sec. 3 and 255 Sec. 24(c) registrations and 266 that have been transferred to a number of different companies, including Syngenta Crop Protection, Incorporated, and 578 that were cancelled outright. There are no granular permethrin formulations among the transferred products.

Sandoz Agro, Incorporated, 11785, 11786, 11787, 50809, 62042, 63374 and 64833, for which there are no existing registrations, 20954 for which there are no active registrations but 135 records consisting of 65 transfers and 5 24(c) registrations, the others cancelled outright, and 55947 for which there are no active registrations but 188 records consisting of 81 transfers and 27 24(c) registrations, the others cancelled outright. There are no granular permethrin formulations among the transferred (to be cont'd)

products.

As to the matter of the rates for the 0.25% product EPA Reg. No. 28293-328 being the same as for the subject product, while it may seem correct that the rates should be half that for the 0.25% formulation, in actual fact, they are the same on all presently registered permethrin ready-to-use granular formulations regardless of whether they are 0.25% or 0.50% in active ingredient. This was determined by examining the label images on the Pesticide Product Label System for the following:

EPA Reg. No. 432-806, "Intercept Lawn Insect Granules" [0.5%]

EPA Reg. No. 9688-83, "Chemsico Lawn Insect Control Granules" [0.25%]

EPA Reg. No. 28293-328, "Unicorn .25% Permethrin Granules"

EPA Reg. No. 51036-322, "Permethrin 0.25% Granules"

EPA Reg. No. 53883-39, "Martin's Surrender Permethrin Granules Lawn Insect Control" [0.25%].

Although the labeling for all these products is not identical in that some of them include directions for certain pests that are not found on others, there is enough similarity to determine that no difference in rates of product applied per unit area occurs among these 5 registrations regardless of concentration of the active.

RL Vern L. McFarland, IB